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FILING DATE: ***October 19, 2004***

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
SHLOMI	BEN ARI	BINYAMINA ISRAEL

Additional inventors are being named on the _____ *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

USING A CATHETER OR GUIDEWIRE TRACKING SYSTEM TO PROVIDE POSITIONAL FEEDBACK FOR AN AUTOMATED CATHETER OR GUIDEWIRE NAVIGATION SYSTEM

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 6 ☐ CD(s), Number _____

☐ Drawing(s) *Number of Sheets* _____ ☐ Other (specify) _____

☐ Application Data Sheet. See 37 CFR 1.76

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Respectfully submitted,

SIGNATURE _____

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Date 5 October 2004

REGISTRATION NO. _____ *(if appropriate)*

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Using a catheter or guidewire tracking system to provide positional feedback for an automated catheter or guidewire navigation system

Provisional Patent

Written by:
Shlomi Ben-ari

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1. Scope

This application provides a description of a novel medical catheterization method based on utilizing a guidewire and/or catheter tracking system to provide position feedback to an automated guidewire or catheter navigation system. It is written in order to be submitted as a provisional patent.

2. Background

Although catheter tracking systems have been in existence for a number of years using a number of different technologies (RF tracking, magnetic tracking, MR Tracking, MRI gradient field tracking, etc...) they have generally been used for special purpose tracking (i.e. cardiac mapping), and not for aiding in navigation during catheterization. This is most likely because the navigation during catheterization is performed primarily with a guidewire and the existing catheter tracking technologies require a tracked element which is too large to be placed on a standard guidewire.

Guidewire and catheter navigation is generally guided by fluoroscopy. This is true for manual catheterization as well as for automated navigation systems such as the magnet driven Niobe navigation system produced by Stereotaxis Inc.

The use of a tiny radioactive source as the tracked element in a catheter or guidewire tracking system, as described in the provisional patent entitled "Utilizing a radioactive source as the tracked element for a tracking system", makes it possible to use such a tracking system as the primary guiding system for the navigation of a guidewire or catheter. Using such a tracking system instead of fluoroscopy has the potential to significantly reduce the radiation dose to the patient and practitioner during intravascular procedures.

3. The invention

3.1. Overview

The invention disclosed here is the use of a guidewire or catheter tracking system as the primary guiding system for an automated catheter or guidewire navigation system. The automated navigation system is capable of applying a force in any direction upon the tip of the guidewire, but in order to navigate the guidewire, it needs real-time feedback about the position of the tip of the guidewire. Current automated navigation systems, such as the Stereotaxis Niobe system, use fluoroscopy to provide this feedback. In addition to being inherently two dimensional (and therefore requiring extra time and processing to produce 3-dimensional information), fluoroscopy guidance results in a high radiation dose to the patient. Replacing the fluoroscopy guidance in such automated navigation systems with a 3-dimensional guidewire tip tracking system will provide real-time 3-dimensional tip position feedback with significantly reduced radiation dose.

3.2. Preferred Embodiment

The system consists of an automated catheter/guidewire navigation system, a C-arm fluoroscopy system (for visualization of the intravascular procedure once navigation to the target location has been completed, blood flow diagnostics, initial 3-D angiography, etc...), and a 3-dimensional guidewire and/or catheter tracking system.

A 3-dimensional angiography data set will either be provided from previous MRI or CT angiography, or will be produced at the outset of the procedure using the fluoroscopy system.

The 3-dimensional angiography data set will be used to produce a 3-dimensional model of the vasculature within which the system will navigate.

The target will then be indicated by the doctor on the 3-dimensional model and the route to the target will be either automatically or manually determined. Once the guidewire is brought into the region of the 3-dimensional vasculature model, the automated navigation system will pull the tip of the guidewire along the predetermined route based on real-time position feedback from the tracking system.

The navigation system computer will control the direction in which the navigation system pulls the guidewire tip at each point in time based on the current tip position provided by the tracking system and the predetermined route on the 3-dimensional vasculature model.

The use of the tracking system for position feedback will reduce both procedure time and radiation dose compared to fluoroscopy guidance.

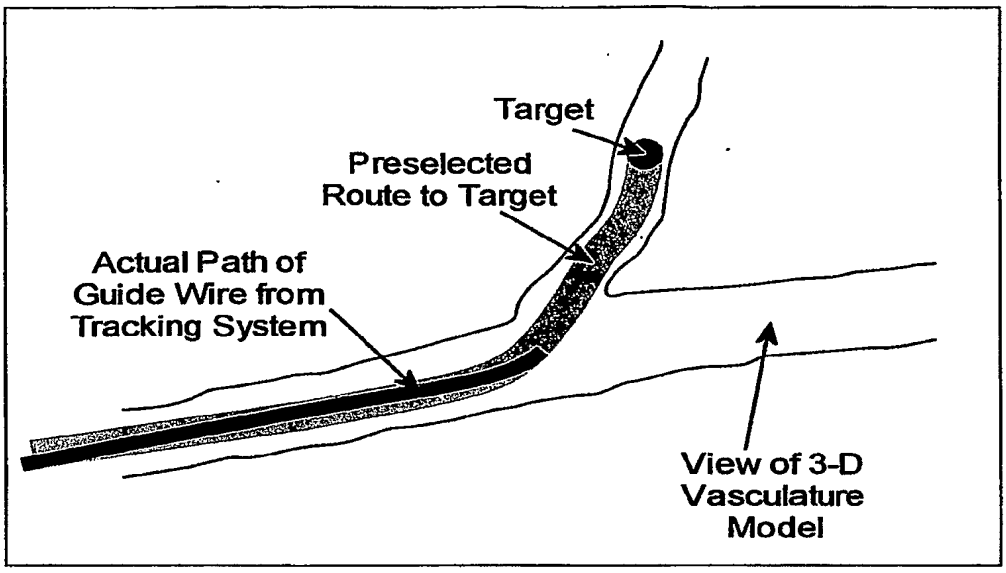

Figure 1 - Example of system display during navigation with elements labeled

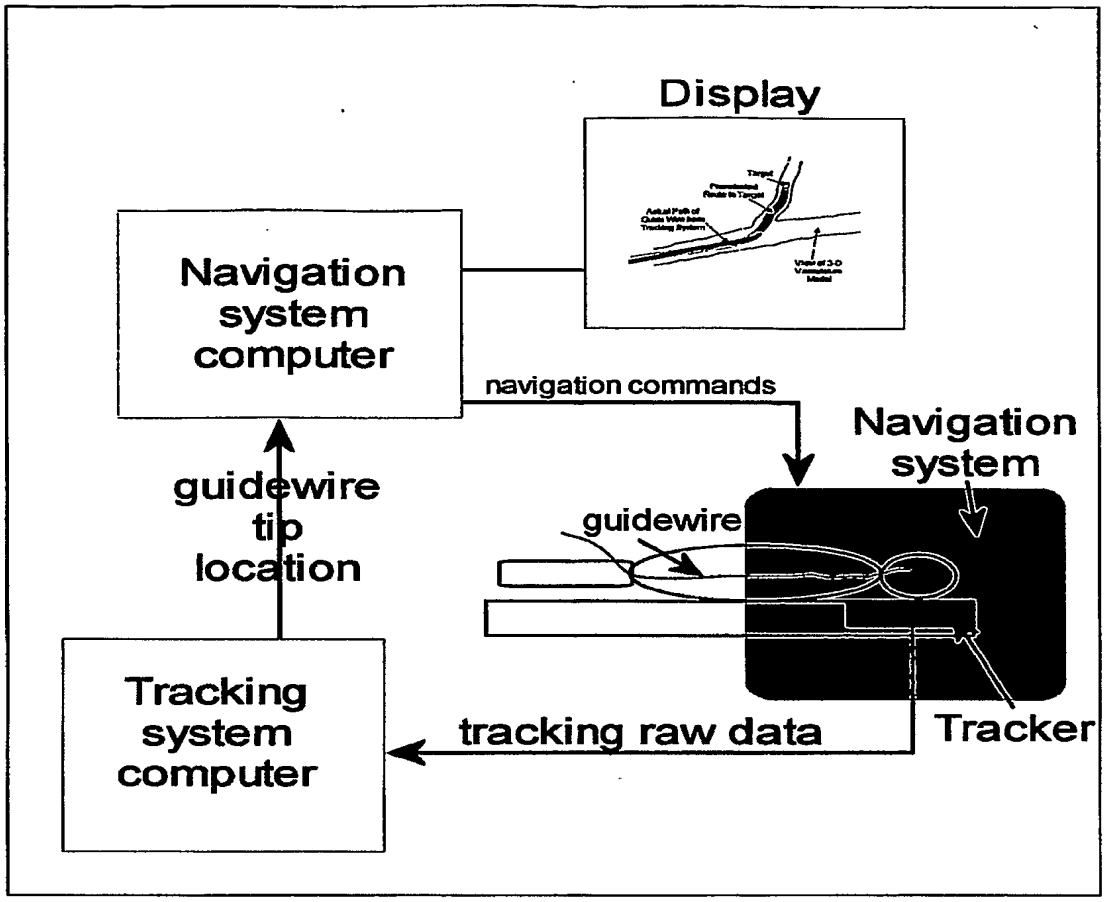

Figure 2 - System Block Diagram with indication of data flow